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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TSAY, MARSHA M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,115	Applicant(s) MORGAN ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,10-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,10-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 15, 2009 has been entered.

Applicants' arguments filed have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2, 7, 9, 17 are canceled. Claims 1, 3-6, 8, 10-16, 18-21 are currently under examination.

Priority: The request for priority to UK 0303999.7, filed February 21, 2003, is acknowledged.

Objections and Rejections

Claims 1, 16 are objected to because of the following informalities: in claim 1, line 8, the terms "total the collagen" should be corrected to "the total collagen"; in claim 16, line 2, there should be an "of" after the term "range." Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1656

Claims 1, 3-6, 8, 10-16, 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the preamble recites an extruded porcine collagen film. However, line 7 recites non-porcine collagen can also be present in said film at less than 10% by weight of the total collagen content in said film. Therefore it does not make sense to recite porcine collagen film in the preamble since non-porcine collagen can also be present in the instant film.

Claim 1, lines 3-5 recite the fat content in the film is reduced to a level below 20% on a dry weight basis and a ratio by weight of collagen to fat in the film is at least 2.5 to 1. This is confusing and does not make sense because if the film has a fat content of 20% (collagen content of 80%), then the ratio of fat to collagen would be 1:4. Therefore, it is unclear how the claim can further recite that the weight of collagen to fat in the film is at least 2.5:1 if the ratio of collagen to fat is at a ratio of 4:1 or below. Further clarification and appropriate correction is requested.

Claim 1 recites "the amount" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 1, line 13, recites the limitation "the extrusion direction" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 3-6 are rejected for the same reasons regarding the weight ratios of collagen to fat that are recited in the claims.

Claims 8, 10-16, 18-21 are included in this rejection because they are dependent on claim 1 and fail to cure its defects.

Art Unit: 1656

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8, 10-16, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 20050031741; previously cited) in view of Eckmayer et al. (US 6482240; IDS, previously cited). For examination purposes, the instant claims have been interpreted as: an extruded porcine collagen film having a fat content, made from an extrudable gel, wherein said film has a ratio by weight of collagen to fat in the film is at least 2.5 to 1; and a collagen content that consists essentially of sow collagen, and wherein said film has a wet tear strength in the extrusion direction greater than 300 gf/mm. Since there are no lower limits to the amount of non-porcine collagen or non-sow porcine collagen derived, claim 1 is reciting a collagen film that has a collagen content consisting essentially of sow collagen. Further, due to the indefiniteness of claim 1, lines 3-5, regarding the ratio of fat to collagen, the ratio of at least 2.5:1 (collagen to fat) is being used for examination purposes.

Morgan et al. disclose collagen casings or film made from an extrudable collagen gel, wherein the collagen is porcine collagen (p. 1 [0001]-[0002]). In working examples 3-4, Morgan et al. disclose a porcine collagen film was prepared from an extrudable porcine collagen gel from sow collagen, having a weight ratio of collagen to fat of around 30:1 (p. 4 [0059]; claims 1, 4-6). The table in paragraph [0062]) indicates a fat percentage of 0.31% and 0.19% for examples 3 and 4, respectively (p. 4; claims 1-3). The porcine collagen casing in example 20 comprises 6.0% of caprine (goat) collagen on a dry weight basis in addition to sow collagen (p. 12; claims 7-8).

Art Unit: 1656

Morgan et al. also disclose that the collagen properties of the casings can be varied by mixing collagen derived from young pigs (4 mos. old) and older pigs (3 yrs. old) in ratios of 0:100 to 100:0 (p. 2 [0019]). Morgan et al. further disclose that the casings have tensile strengths in the extrusion direction of at least 2.5 kg (p. 2 [0023]). Morgan et al. do not explicitly teach the collagen casing is in another film besides a tube.

Eckmayer et al. disclose a method of producing a porcine collagen film comprising defatting porcine skins by mechanical means (col. 4 line 64), forming a gel-like fluid mass (col. 8 lines 17), and extruding the gel to form a film and/or membrane (col. 10). Eckmayer et al. disclose the collagen film can be used as a net to wrap around ham (col. 12 lines 16-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Morgan et al. by extruding the collagen gel to form a film as suggested by Eckmayer et al. instead of as a thin-walled tube (claims 1, 3-6, 8). The motivation to do is given by Eckmayer et al., which disclose that collagen membranes can be extruded from collagen gels and formed into a film to wrap around a food product. It would be reasonable for one of ordinary skill to recognize that a collagen membrane formed into a film can have broader applications than a collagen membrane formed into a tube shape, i.e. casing, and that both are obvious variations that can be made from collagen since Morgan et al. disclose both terms within their patent.

Although Morgan et al. or Eckmayer et al. do not specifically disclose the limitation of a wet tear strength greater than 300 gf/mm, it would be reasonable for one of ordinary skill to recognize that this property would be present in the collagen product of Morgan et al. in view of Eckmayer et al. since Morgan et al. disclose an extruded porcine collagen product that meets the

Art Unit: 1656

limitations of instant and has a tensile strength of at least 2.5 kg with no upper limit, which would meet the instant limitation of a strength greater than 300 gf/mm since claim 1 also does not recite an upper limit.

Further, in example 12, Morgan et al. disclose a sow porcine collagen casing with a humectant (i.e. glycerol) level of 21.5% on a dry weight basis (p. 8-9; claims 13-14). The collagen casing in example 16 comprises propylene glycol alginate (p. 10; claims 10-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further incorporate humectant and alginate glycol in the porcine collagen film of Morgan et al. in view of Eckmayer et al. (claims 10-14). The motivation to do so is given by Morgan et al. which disclose that humectant and alginate glycol can be incorporated into a collagen membrane.

In example 9, Morgan et al. teach the porcine casing further comprises glutaraldehyde (p. 6 [0128]; claim 15). Also, the collagen casing has a collagen solids content of 7% (p. 13-14; claim 16). In example 1-4, Morgan et al. teach the porcine collagen casings were used to make sausages (p. 3-4; claim 21). The casing of Morgan et al. can also be used to make edible string and/or netting (p. 2 [0022]; claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate glutaraldehyde and have a solids content of 7% into the porcine collagen film of Morgan et al. in view of Eckmayer et al. (claims 15-16). It would also have been obvious to know that said porcine collagen film of Morgan et al. in view of Eckmayer et al. can be used to wrap a food product or be further formed into a string or netting (claims 18, 21). The motivation to do so is given by Morgan et al., which disclose that glutaraldehyde and solid

Art Unit: 1656

contents can be added into a collagen membrane that can be used to wrap a food product or formed into a string or netting.

Further, Morgan et al. teach a method of producing an extruded porcine collagen film from sow collagen comprising soaking sow skins, removing fat by a fleshing machine (p. 3 [0032]), forming an extrudable gel from the sow skins by blending and disintegrating porcine skin (p. 3 [0039]), and extruding the gel to form a casing (p. 3 [0040]-[0045]) (claims 19-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a collagen membrane by the method of Morgan et al. and form said membrane into a film as suggested by Eckmayer et al. (claims 19-20). The motivation to do is given by Morgan et al. which disclose a method of making a porcine collagen membrane and Eckmayer et al. which disclose extruded collagen can be formulated into a film.

In their remarks, Applicants assert that (1) again, one of skill in the art considers the terms “film” and “casing” have exclusive and separate meanings. The examiner has not provided support for the broad and conclusory allegation that one of skill in the art would appreciate that a film or a casing are merely different physical forms of an extruded collagen membrane. The examiner, in the previous Office action, notes that Morgan et al. do not explicitly teach the collagen can be in another form besides a tube. (2) Eckmayer et al. disclose collagen membranes (films) formed from porcine rinds (i.e. pig skins). However, Eckmayer et al. is silent in regard to preparing a collagen film that has a collagen content that consists essentially of sow collagen as instantly claimed. (3) Applicants have purposefully selected and manufactured collagen film from mainly sow collagen. There is no teaching or suggestion in the

Art Unit: 1656

prior art that one of ordinary skill in the art at the time of the invention to prepare a collagen film from sow collagen without applying hindsight in light of the present application.

Applicant's arguments filed have been fully considered but they are not persuasive.

(1a) Applicants continue to maintain that the terms “film” and “casing” have exclusive and separate meanings. It is acknowledged that the terms "film" and "casing" have different meanings, which is why Morgan et al. is applied as a 103(a) reference. However, it would be reasonable for one of ordinary skill to know that a "film" and “casing” are obvious variations of a collagen membrane since both terms are disclosed together in the Morgan et al. reference. Further, it should be noted again that the instant specification discloses the terms “film” and “casing” together and in the alternative, i.e. film or casing (specification p. 2-3).

Instant claim 1 is drawn to a porcine collagen film having a fat content wherein said film has a collagen content that consists essentially of sow collagen. As noted above, Morgan et al. disclose a collagen casing having a fat content wherein said casing has a collagen content that consists essentially of sow collagen. Morgan et al. further disclose the terms collagen "film" and/or "casing" together (p. 1 [0002], [0008]). Therefore, since Morgan et al. disclose a collagen product that has the same components as the instant collagen product, it would be reasonable for one of ordinary skill to recognize that said collagen casing of Morgan et al. can easily be formed into a film since both terms are disclosed in Morgan et al. This is further supported by Eckmayer et al. which disclose that collagen membranes in general can be formulated into a film. It would be reasonable for one of ordinary skill to recognize that even if Morgan et al. do not explicitly disclose a working example of a porcine collagen film, the extruded collagen membrane of

Art Unit: 1656

Morgan et al. can easily be formulated into a "film" for broader applications, i.e. to wrap around a ham or some other type of food product, since Eckmayer et al. disclose analogous extruded collagen membranes from porcine skins can have the form of a film. One of ordinary skill could easily see that extruded collagen membranes can have different physical forms, i.e. casing or film. A similar analogy would be a product being in the form of a lotion or a cream. Both lotion and cream are just different physical forms of the same product. It should also be noted that a "casing" when stretched around a food product would be a "film" around said food product.

(2a) It should be noted that the Eckmayer et al. reference was merely cited to note that porcine collagen films can be formed by an extrusion process. Since Morgan et al. disclose an extrusion process using sow collagen to form casings, it would be obvious to one of ordinary skill to know that said extrusion process using sow collagen of Morgan et al. can also form films since Eckmayer et al. disclose analogous collagen proteins can be successfully extruded into a film. It should also be noted that a "casing" when stretched around a food product would be a "film" around said food product.

(3a) Morgan et al. disclose the use of sow collagen throughout all their working examples. Applicants are directed to p. 15, claim 21, of Morgan et al., which discloses the porcine collagen can be derived from sow hides. On page 3 [0032], Morgan et al. disclose a general method of producing an extruded porcine collage film comprising removing fat, forming an extrudable gel, and extruding the gel to form a casing (p. 3 [0040]-0045]). Further, many of the working examples disclosed by Morgan et al. use sow hides (examples 3-12, 18, 21-22), which one of ordinary skill would know to substitute sow hides into the general method of

Art Unit: 1656

producing an extruded porcine collagen film as disclosed on page 3 [0032], [0040]-[0045]).

Regarding the terms “film” or “casing”, see arguments in (1a) and (2a).

For at least these reasons, the 103(a) reference is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

July 14, 2009